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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/007,385    01/15/98    CHU

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NEW YORK NY 10022

HM12/0504

EXAMINER
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TURNER, S

ART UNIT	PAPER NUMBER
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1644

15

DATE MAILED: 05/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

09/007,385

Applicant(s)

Hsien-Jue

Examiner

Sharon L. Turner, Ph.D.

Group Art Unit

1644



☒ Responsive to communication(s) filed on 11-22-99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 2-21 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 2-21 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### **Response to Amendment**

1. The Examiner and Art Unit of U.S. Patent application SN 09/007,385 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1644.
2. Finality has been withdrawn. The amendment filed 11-22-99 has been entered into the record and has been fully considered.
3. Claim 1 has been canceled. Claims 2-21 are pending.
4. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

### **New Rejections**

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites the limitation "the composition of claim 1". There is insufficient antecedent basis for this limitation in the claim because claim 1 has been canceled. Claims 11-14

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depend from claim 10 and thus also lack antecedent basis. Similarly, claim 15 recites the limitation "a composition of claim 1". There is insufficient antecedent basis for this limitation in the claim because claim 1 has been canceled. Claim 16 depends from claim 15 and thus also lack antecedent basis.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,183,659, Timoney et al, 2 February, 1993, in view of EP0786518 A1, Hartford et al, 24 January 1997, and US Patent No. 5,597,807, Estrada et al., 28 January 1997.

Timoney et al, previously of record, teach a live non-encapsulated attenuated *S. equi* strain designated strain 70-297 (ATCC 53185) which is identical to applicants *S. equi* strain 70-297 deposited as ATCC Accession No. 53186. Applicants argue that this strain is publicly available since 1993, see Amendment A, Paper No. 5, mailed 3-26-99, paragraph spanning pp. 2-3. This strain is applicants preferred embodiment as recited in instant claims 5, 9, 11-14, 16, and 18. The page and line references cited herein are in respect to the '659 patent. Timoney teach that the vaccine may be administered either intranasally (mucosally) or orally see in particular

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abstract, that the vaccine is avirulent (attenuated) see in particular column 2, lines 57-64, and stimulates an immunological response which produces major IgG and IgA antibody in the nasopharyngeal mucus see in particular column 3, lines 40-45 and Figure 1. The strain is avirulent at  $3 \times 10^9$  CFU when inoculated intranasally or orally. The strain is nonencapsulated, in particular column 4, lines 53-55. Vaccination either intranasally or orally at  $3 \times 10^9$  CFU produced resistance to challenge with wild-type virulent strain, see in particular Figure 2.

Timoney et al do not teach the above vaccine in combination with an immunostimulant, the immunostimulant having the property of stimulating mucosal immunity.

Hartford, EP0786518 teach a protective live attenuated nasal mucosa *S. equi* vaccine in combination with an immunostimulant which comprises Quil A (saponin) adjuvant to enhance the immune response of the host, see in particular p. 3, lines 39-46. Hartford does not expressly teach that Quil A saponin adjuvant has the property of stimulating mucosal immunity.

US Patent No. 5,597,807, Estrada et al teach Quinoa saponin compositions and methods of use. In particular, Estrada teaches Q. saponin compositions useful as immunological adjuvants, to stimulate nonspecific immunity, to enhance an immunological response to a selected antigen and to enhance mucosal absorption of a drug, see in particular abstract, column 1, lines 48-67. Estrada teaches the discovery that Q. Saponin composition can promote mucosal immunity, i.e., the production of IgG and IgA antibodies and enhances both humoral and secretory immune responses in vertebrates when administered with a selected antigen, see in particular column 5, lines 39-45. Estrada also teaches that Q. saponins enhance nonspecific

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immunity and cause increased absorption through mucosal membranes, see in particular column 6, lines 57-67. Estrada teaches that Q. saponins can be used as immunological adjuvants in vaccine compositions and absorption adjuvants, including against selected bacterial pathogens, see in particular column 6, lines 13-67. Estrada teaches in saline doses of Q. saponins at 2 $\mu$ g-10mg, see in particular Table 1 and with antigens of from .1-1000 $\mu$ g, see in particular column 8, lines 5-8.

Thus, Hartford teaches the benefit of combining a live attenuated nasal mucosa *S. equi* vaccine with an immunostimulant adjuvants, specifically Quil A , a saponin. Estrada teaches that Quinoa (Quil A) saponins provide the properties of enhancing mucosal immunity, increased mucosal antigenic absorption and stimulation of secretory IgG and IgA antibody.

Thus, it would have been prima facie obvious to one of skill in the art to modify the Timoney nasal (mucosal) vaccine by adding a Quil A saponin mucosal adjuvant to achieve the beneficial effects of enhanced mucosal immunity. One of skill in the art would be motivated to perform such modifications based on the teachings of the beneficial results of the adjuvant in *S. equi* vaccines, the effectiveness of Quil A saponins in vaccines producing enhanced mucosal immunity. One of skill in the art would have expected success using these methods based on the protective properties of the *S. equi* vaccines of Hartford and Timoney, and the beneficial results of an adjuvant as taught by Hartford and Estrada in producing enhanced mucosal immunological responses. Thus, the reference teachings render the claimed invention obvious.

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### Status of Claims

9. No claims are allowed.
10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973.

Sharon L. Turner, Ph.D.  
May 1, 2000

*Patricia A. Duffy*  
PATRICIA A. DUFFY  
PRIMARY EXAMINER